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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,227	11/12/2003	John D. Pruitt	029318-0985	3550
31049 7590 10/30/2007 ELAN DRUG DELIVERY, INC. C/O FOLEY & LARDNER LLP 3000 K STREET, N.W. SUITE 500 WASHINGTON, DC 20007-5109			EXAMINER FUBARA, BLESSING M	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 10/30/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/705,227

Applicant(s)

PRUITT ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 27 and 31-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26, 28-30 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/22/04 & 5/10/04.
- ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of response to election/restriction requirement filed 04/09/07, response to correspondence of 7/12/07 filed 8/13/07, IDS filed 5/10/04 and 4/22/04, change of address filed 6/09/2006 and preliminary amendment to the specification filed 4/22/04.

1. Applicant's election with traverse of Group I, claims 1-32 and 37, and polyvinylpyrrolidone and meloxicam in the reply filed on 04/09/07 and 8/13/07 is acknowledged. The traversal is on the ground(s) that search and examination of the claims do not present undue burden to the examiner. This is not found persuasive because the claimed product/dosage form of claim 1 can be prepared by materially different method.

The requirement is still deemed proper and is therefore made FINAL.

Applicant elected meloxicam that is not disclosed in original specification and as such the drugs in claim 26 are searched. Claim 27 directed to neutraceutical, claims 31 and 32 that are concerned with cationic surface stabilizers are withdrawn from examination. Claims 27 and 31-36 are withdrawn.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-17, 25, 26 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Murakami et al. (US 6,287,596) or Shimizu et al. (US 6,299,904).

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Murakami discloses fast disintegrating compression molded product/tablet (abstract; column 4, lines 24-63; column 7, lines 11-15) comprising pharmaceutically active agents listed in column 5, line 61 to column 6, line 67 meeting the requirements of claims 1 and 26, lubricants, diluents, coloring agents with the diluents being lactose or glucose or sucrose and the binders being acacia or pullulan or polyvinylpyrrolidone, flavoring agents, effervescent agents such as combinations of tartaric acid, malic acid and sodium carbonate or sodium bicarbonate (column 7, lines 13-45), and the pullulan and the effervescent couple meeting claims 1, 4, 5, 7-11, 14-16, 25 and 26. Claim 17 is the property of the product so that Murakami meets the claim. Friability is a property of the product; the disintegration time of the product of Murakami is in the order of seconds (column 9, lines 13-43) meeting claim 14; Murakami teaches that the rapidly disintegrating compression molded material is orally administered to infants and aged adults for the treatment of variety of diseases (column 9, lines 44-60; column 10, lines 34-40) meeting claim 37.

Shimizu describes composition that disintegrates fast and comprises drug listed on column 2, line 5 to column 4, line 59, one or more sugars, additives such as binders, acids, foaming agents, lubricants, stabilizers, flavorants, disintegrants, pullulan, gum arabic and (column 5, lines 44-67), citric acid, tartaric acid or malic acid and carbonates (column 6, lines 16, 17; column 7, lines 7-13); the preparation is useful for treating hypertension, cardiac diseases, cerebral apoplexy and renal failure when the active agent is candesartan cilexetil (column 8, lines 44-50).

4. Claims 1, 4, 5, 7, 8-17, 25, 26 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Martyn et al. (in WO 00/50013).

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Martyn discloses rapidly soluble composition that contains active agent (page 5, line 10 to page 7, line 36), pullulan (page 2, line 35; page 3, line 24), suitable excipient such as lactose and maltose and sorbitol (page 4 line 32). See also claims 1-10. Friability is the property of the claimed product. The release rate recited in claim 13 is inherent to the composition of Martyn.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 18-24 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murakami et al. (US 6,287,596).

Murakami is described above for disclosing a composition containing pullulan, effervescent couple, lactose and active agent. The composition of Murakami also contains surfactants (column 7, lines 43-49) meeting claims 21 and 28-30. Regarding claims 18-20, active agents are generally obtained in powder forms and the particles of the powder have sizes

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that meet the limitations of claims 18-20. Regarding the amounts of the active agent and surface stabilizer, the claims 22-24 would have been obvious because the ordinary skilled artisan have the capabilities to use desired amounts of active agents and surface stabilizers in the composition Murakami for a rapidly disintegrating material.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is directed to solid dosage form and the requirement that the solid dosage form is an aerosol formulation in claim 13 is unclear since fluids are not solids. Clarification is respectfully requested.

10. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Blessing Fubara
Patent Examiner
Tech. Center 1600

A handwritten signature in black ink, appearing to read "Blessing Fubara", is written over the printed name.